IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANTS' OBJECTIONS TO PTO #27

Pursuant to Rule 72 of the Federal Rules of Civil Procedure, Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC ("Defendants"), by and through counsel, respectfully submit their objections to PTO #27 regarding the scope of discovery.

I. INTRODUCTION

On July 1, 2009, United States Magistrate Judge Mary E. Stanley issued PTO #27, specifically noting that the allegations in this litigation involve the alleged improper dosages of the active pharmaceutical ingredient in Digitek® – digoxin. (ECF No. 150 at 12.) She also noted that: 1) Defendants produced Digitek® "uniquely, with equipment which was not widely used for other products" (*id.* at 15); and 2) "Plaintiffs' contention that an incident involving one product 'would be similar or even identical' to an incident involving Digitek® is too speculative to justify the enormous and expensive expansion of the discovery they seek." (*Id.* at 15.) But in an attempt to "strike the balance," she permitted a limited expansion of the scope of discovery to non-Digitek® products. (*Id.*) Specifically, PTO #27 permits Plaintiffs to obtain "records of Little Falls production and the use of equipment for products other than Digitek®, which

immediately preceded the use of that equipment for the production of Digitek®. That is, if the 50 cubic foot blender was used to blend a product other than Digitek®, ("product A"), and the blender was next used to blend Digitek® or one of its precursors, then the scope of discovery will include the batch record for product A." (*Id.*)

Defendants assign the following errors:

1) PTO #27 should be vacated because the Magistrate Judge specifically found that Digitek® was manufactured uniquely, and that it would be too speculative to expand discovery from one product to another, yet permitted discovery of non-Digitek® product information in her conclusion. The relief ordered is at odds with her factual findings and the factual evidence of record;

2) The Magistrate Judge's finding that information in non-Digitek® records might lead to relevant evidence should be vacated because there is no factual evidence of record to support the finding and in fact, there is sworn evidence of record to the contrary;

3) The Magistrate Judge's reliance on FDA letters to expand discovery is legally and factually erroneous. The FDA letters make no observations about Digitek® in regard to digoxin dosage – the issue in this litigation – and the references to "adulteration" in these letters have a specific meaning under federal regulations; that meaning has no bearing on whether a drug is deemed "safe" or "unsafe" under the regulations, or legally "defective"; and

4) PTO #27 does not reflect that the Magistrate Judge, in entering her compromise order, weighed the burden and expense to Defendants against the relevancy or

benefit of the expanded discovery; because the documents are irrelevant, Plaintiffs should bear some portion, if not all, of the cost associated with producing non-Digitek® documents if PTO #27 is not vacated.

II. FACTS

In addition to the facts set forth in the parties' briefs and PTO #27, Defendants highlight the following key facts:

1) The FDA, in the letters attached to the motion papers, made no findings about out-of-specification Digitek®;

2) There is no relationship between a "cleaning validation" issue and an "out-of-specification" issue. (*See* Affidavit of Richard Dowling ("Dowling Aff."), attached as Exh. A, at ¶¶ 4-5); and

3) Equipment cleaning records are kept separately – not as part of lot manufacturing records – and they have already been produced in this litigation (Dowling Aff., ¶ 3).

III. STANDARD OF REVIEW

Under 28 U.S.C. § 636(b)(1) and Federal Rule of Civil Procedure 72, Defendants may object to a Magistrate Judge's order of a non-dispositive matter within 10 days after being served with a copy. Fed. R. Civ. P. 72(a). "Matters concerning discovery generally are considered 'nondispositive' of the litigation." *Thomas E. Hoar, Inc. v. Sara Lee Corp.*, 900 F.2d 522, 525 (2d Cir. 1990). "The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a). Under Rule 72(a), "[a] finding is 'clearly erroneous' when, although there is evidence to support

it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Concrete Pipe and Products of Cal., Inc. v. Constr. Laborers Pension Trust for South. Cal.*, 508 U.S. 602, 622 (1993) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)); *Harman v. Levin*, 772 F.2d 1150, 1153 (4th Cir. 1985). An order is contrary to law "when it fails to apply or misapplies relevant statutes, case law or rules of procedure." *Tompkins v. R.J. Reynolds Tobacco Co.*, 92 F. Supp. 2d 70, 74 (N.D.N.Y. 2000) (citation and internal quotations omitted).

IV. ARGUMENT

A. The relief ordered is at odds with the Magistrate Judge's factual findings and the factual evidence of record.

The Magistrate Judge correctly found that it would be pure speculation to connect an incident involving a non-Digitek® product batch to a Digitek® batch:

> Plaintiffs' contention that an incident involving one product 'would be similar or even identical' to an incident involving Digitek is too speculative to justify the enormous and expensive expansion of discovery they seek.

(ECF No. 150 at 15.) Yet that is exactly what PTO #27 does, though in a more limited way than Plaintiffs requested. The relief ordered under PTO #27 is inconsistent with the Magistrate Judge's factual findings: 1) about the speculative nature of the basis for Plaintiffs' requested relief; and 2) that Digitek® is "uniquely" manufactured "with equipment which was not widely used for other products." (*Id.*)

Internal inconsistency rises to the level of clear error. *Dvorak v. Metropolitan Life Ins. Co.*, 965 F.2d 606, 610 (8th Cir. 1992) (internal inconsistency rendered decision implausible on its face); *Nobles v. MBNA Corp.*, 2007 WL 4171134 (N.D. Cal. 2007) (vacating decision to give

Magistrate Judge opportunity to achieve consistency). The error in PTO #27 is that it creates a limited exception – with no factual support – to the Magistrate Judge's initial factual findings. As discussed in the following section, there is no basis for the exception.

B. The Magistrate Judge's decision that information in non-Digitek® records might lead to relevant evidence is erroneous.

After correctly finding that a general expansion of discovery to information about non-Digitek® products was not warranted, the Magistrate Judge nonetheless permitted an expansion of discovery, explaining that "digoxin tablets were among the products with inadequate cleaning validation." (ECF No. 150 at 13.) She then hypothesized that "[i]f records indicate that a blender was used for product A and was immediately thereafter used for Digitek®, a fair assumption can be drawn that the blender was not cleaned between uses." (*Id.* at 15-16.) This assumption – the foundation of the Magistrate Judge's limited exception – is incorrect for two reasons.

First, as the Magistrate Judge acknowledged, the claim in this litigation is not cross-contamination from other products; it is the alleged improper dosage of digoxin, the active pharmaceutical ingredient in Digitek®. (ECF No. 150 at 12.) While Judge Stanley noted that there was an observation about inadequate cleaning validation studies concerning digoxin tablets in one of the FDA letters, that is no basis on which to broaden the scope of discovery to non-Digitek® products, no matter how limited. (*Id.*)

As explained in Defendants' Brief in Opposition, discovery should by limited to the allegations within the Complaint. *See, e.g., State of Missouri ex rel. General Motors Acceptance Corporation v. Standridge*, 181 S.W.3d at 77-78 (trial court abused its discretion where discovery requests were not tied to the parameters of the counterclaim). There has never been an

allegation in this case about cleaning issues or cross-contamination. The allegation is that Digitek® contained too much or too little digoxin. Factually, there is no relationship between a cleaning validation issue with a non-Digitek® product, and a digoxin dosage issue with Digitek®. (Dowling Aff.,¶¶ 4-5.)

Second, the Magistrate Judge's assumption is incorrect on relevancy grounds. There are two key facts to this analysis: (1) the cleaning of equipment following its use to make a non-Digitek® product has absolutely nothing to do with the amount of digoxin in Digitek® that went to market, and plaintiffs do not claim that active ingredient from non-Digitek® drugs was in Digitek® tablets; and (2) the batch records do not reflect the equipment cleaning even if there were some remote connection. (Dowling Aff, ¶ 3.) The cleaning logs, which have been produced, contain this information. These two key facts establish that the information the Magistrate Judge finds discoverable under PTO #27 is not relevant to plaintiffs' claims. Beyond the lack of relevancy, the Magistrate Judge clearly erred in concluding that batch records would even contain cleaning notations.

Rule 26(b)(1) provides that discovery may be had regarding any matter that is "relevant to any party's claim or defense . . . " and that "[r]elevant information need not be admissible at the trial if the discovery appears to be reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). But the admissibility/non-admissibility issue is still expressly couched in terms of relevancy. The two key facts above establish that the Magistrate Judge's assumption – that a "blender was not cleaned between uses" (ECF No. 150 at 15-16) – would not lead to the discovery of relevant evidence. The assumption is thus an erroneous basis on which to justify expanded discovery, constituting clear error.

Likewise, the Magistrate Judge's second example to support a limited expansion of non-Digitek® information lacks factual support. She states: "If compression and tableting equipment was used for product B immediately before a batch of Digitek®, then the batch record and associated testing data for product B is discoverable, including any indications of equipment malfunctions or the use of inappropriate dies." (ECF No. 150, ¶ 16.) This suggests that if there was a compression problem on the product run before Digitek®, there might have been a compression problem when Digitek® was run. Yet there is absolutely nothing in the record to support this suggestion – and overwhelming evidence to negate it. The Dowling Affidavit attached to Defendants' Brief in Opposition to Plaintiffs' Motion to Expand the Scope of Discovery (ECF No. 146, Exh. B) directly contradicts any such suggestion. That testimony establishes that the manufacturing process for Digitek® is unique, and bears no reasonable or relevant relationship to the manufacturing process for non-Digitek® products. (*Id.*) In addition, the Magistrate Judge's example is at odds with her initial factual findings of "uniquely" manufactured, and the speculative bases on which Plaintiffs sought expanded discovery. Moreover, the use of an inappropriate die for one product has no relevance to Digitek®, which is made with its own unique die and punch set. (*Id.*) The die and punch set for a non-Digitek® product would not be reflected in Digitek® batch records, or vice versa.

In sum, the Magistrate Judge's reasons to expand discovery are either erroneous (the cleaning exception) or without any support in the record (compression). Her initial factual findings were correct – the error lies in trying to justify limited exceptions with no basis in the facts of record.

C. The Magistrate Judge's reliance on FDA letters to expand discovery is legally and factually erroneous.

The Magistrate Judge quotes from the FDA warning letters, suggesting that the FDA's observations should have some bearing on the scope of discovery in the Digitek® cases. She explains that the 2006 and 2007 warning letters "constitute evidence that inspectors with knowledge of pharmaceutical manufacturing were not satisfied with Defendants' compliance with applicable federal regulations, current good manufacturing practices, including cleaning and maintenance of manufacturing equipment, and effective quality control." (ECF No. 150 at 13.) The issues of cleaning and compression have been addressed; Defendants' general compliance with federal regulations and manufacturing practices are likewise irrelevant to this litigation because Plaintiffs have no legal right to enforce the Food, Drug, and Cosmetic Act or its implementing regulations. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 824 (3d Cir. 1998) ("It is . . . well established that Congress has not created an express or implied private cause of action for violation of the FDCA."); *Kemp v. Medtronic, Inc.*, 1999 WL 34783863, *13 (S.D. Ohio 1999) ("However, the Plaintiffs' negligence per se claim alleges only that Medtronic failed to comport with the FDA's good manufacturing regulations . . . there is no private right of action for such a claim."). Defendants have filed a dispositive motion on this very issue. *See* Defendants' Motion to Dismiss Count V of the Master Consolidated Complaint for Individuals (ECF No. 102).

Even if the FDA letters were proper guideposts to establish the scope of discovery, they actually show that other Digitek® batches are the only products reasonably related to Digitek® manufacturing. For example, Magistrate Judge Stanley quotes Observation 6 from the FDA's May 20, 2008 letter, noting that:

> Of concern is the FDA's observation that '[i]nvestigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.'

(ECF No. 150 at 15.) The FDA letter then goes on to explain how this general observation specifically applies to Digitek®:

> Although QA investigation 07-093, dated 1/25/08, for double thick Digoxin Tablets 0.125 mg, lot # 70924A1, did not establish a root cause for the defective tablets, the investigation was not expanded to evaluate all finished product lots or strengths of Digoxin Tablets. At the time of inspection there were approximately 89 lots of Digoxin Tablets 0.125 mg and 78 lots of Digoxin Tablets 0.250 mg on the market within expiry.

(ECF No. 147, Exh. 2.) In short, the FDA determined that Defendants should have investigated other lots of *Digitek*® tablets, not *other products that contain no digoxin.*

Moreover, the letters do not establish that any other product had too much or too little digoxin, or that any other product influenced the digoxin dosage in Digitek® tablets. Judge Stanley mistakenly relied upon references to "adulterated" drugs in the FDA letters to expand the scope of discovery in this action:

> In light of the FDA warning letters, if the court were to refuse to expand discovery to records which reflect the use or misuse and operation or malfunctioning of equipment immediately before each batch of Digitek®, Plaintiffs would be unduly limited in their ability to determine whether a given batch of Digitek® was more likely than not "adulterated" and/or associated with an adverse drug event, other injury or death.

(ECF No. 150 at 16.) Beyond the fact that there is no private cause of action under the FDCA or its implementing regulations, the reference to "adulterated" in these letters does not mean "unsafe," "ineffective," or "defective" under the plain language of the statute. A drug is

"adulterated" under 21 U.S.C. § 351(2)(B) if the "methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. . . ." As established by the FDA, violations of current good manufacturing practices may result in a warning letter and an "adulterated" status under 21 U.S.C. § 351(2)(B). But "adulterated" under 21 U.S.C. § 351(2)(B) is not defined as, and therefore *not the equivalent of*, "unsafe," "ineffective," or "defective" to a degree that precludes the continued manufacture and sale of the product to the consumer level. *See U.S. v. Bhutani*, 175 F.3d 572, 578-79 (7th Cir. 1999) (adulterated" is not equivalent to "unsafe" or "ineffective").

D. The Magistrate Judge did not weigh the additional burden and costs that would be imposed on Defendants as a result of her compromise order against the relevancy or benefit of the expanded discovery.

While the Magistrate Judge acknowledged the "enormous and expensive expansion" of the discovery Plaintiffs sought (ECF No. 150, at 15), she did not weigh the *additional* burden or costs Defendants would have to bear to comply with her compromise approach, against the relevancy or benefit of the expanded discovery. Federal Rule of Civil Procedure 26(b)(2)(C)(iii) provides:

> **(C)** . . . On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:
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> * * *
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> **(iii)** The burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

See, e.g., Evans v. Visual Technology, Inc., 1994 WL 28002 (N.D.N.Y. 1994) (while a magistrate judge is afforded broad discretion with respect to discovery matters because no one factor controls, the magistrate judge must balance the need for the information sought against the burden of producing it and the exposure to irreparable harm); *U.S. v. Flowers*, 372 F. Supp. 2d 1319, 1326 (M.D. Ala. 2005) (in assessing plan for "more extensive, but still quite limited, discovery" magistrate judge was to consider not only relevancy of additional discovery, but whether discovery order would cause future disputes that would quickly overwhelm the parties and the court).

The Magistrate Judge did not weigh the cost and burden of her compromise order on Defendants, or the amount of time it would delay the case, against the relevancy or benefit of the expanded discovery. (ECF No. 150). The Actavis Defendants are in the process of producing numerous batch records regarding Digitek®. The approximate cost to produce records concerning Digitek®, only, is conservatively estimated at $6 million (ECF No. 146, Exh. C, ¶ 17). Defendants have made a preliminary assessment of the number of additional batch records that PTO #27 would require them to produce. The additional burden that PTO #27 would impose on Defendants is significant and would not only impact Defendants but would also disrupt this litigation.

Defendants' initial assessment of the practical impact of PTO #27 indicates Defendants would be required to produce batch records for at least 80 batches of non-Digitek® product. This is more than half the total number of Digitek® batches for which Defendants have produced batch records. Collecting, scanning, processing, preparing, and producing just the Digitek® documents to Plaintiffs in the agreed-upon electronic format has taken Defendants many months. None of

the non-Digitek® batch records have even been collected because Defendants could not reasonably have anticipated that records relating to the production of these specific batches would be ordered.

To comply with PTO #27, Defendants would be required to suffer substantial additional business interruption to identify, collect, and scan the appropriate records, which would then have to be reviewed, processed for inclusion in the electronic database hosting Defendants' documents, and finally processed and put into the agreed-upon format for service on Plaintiffs. To get these additional documents from their current uncollected status to being produced to Plaintiffs would take several months, even if Defendants were not currently engaged in any other document production activities. Adding the collection and production of these documents to Defendants' current document production obligations and activities could delay finalizing Defendants' document productions by 3-5 months. Defendants would also incur substantial additional costs associated with on-site collection and scanning, document review, and document processing required to prepare and produce these additional documents.

Imposing these additional burdens on Defendants is not justified considering the reality that the batch records of these non-Digitek® products will reveal absolutely nothing about whether the Digitek® ingested by any plaintiff had too much or too little of the active pharmaceutical ingredient in Digitek®. The Magistrate Judge failed to weigh these burdens against the relevancy or benefit of the expanded discovery. Her failure to do so was erroneous.

For this reason, should PTO #27 remain in place, Plaintiffs should bear some portion, if not all, of the cost associated with producing the irrelevant, non-Digitek® documents. *See Oppenheimer Fund, Inc. v. Sanders,* 437 U.S. 340, 358 (1978) (stating that district courts may, in

their discretion, condition discovery on the requesting party's payment of costs); see also In re Application of Michael Wilson & Partners, 2009 WL 1193874, at *2, 8-9 (D. Colo. Apr. 30, 2009) (ordering the requesting party to post a cost bond where the parties were required to share equally the cost of imaging, preserving, searching, and producing the requested documents); 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, FEDERAL PRACTICE AND PROCEDURE, § 2038 (2d ed.1994) (stating that the "court may order the party seeking discovery to pay the expenses caused thereby though it is not required to do so") (citations omitted). Cost sharing, if not bearing the total cost, is particularly justified in light of the FDA's recent July 8, 2009 public statement about Digitek®, setting forth the agency's position that "harm to patients was very unlikely."[1]

[1] http://www.healthnewsdigest.com/news/Family_Health_210/Fact_and_Myths_about_Generic_Drugs.shtml.

V. CONCLUSION

Defendants respectfully request that the court vacate PTO #27 and determine that the scope of discovery should not be expanded to include products other than Digitek®. There is nothing in the record before the Court to suggest that any problem encountered with another product might lead to relevant evidence about the amount of active ingredient in Digitek® manufactured during the relevant timeframe. The Magistrate Judge was correct in her conclusion that Digitek® was manufactured uniquely, and that the bases on which to expand discovery beyond Digitek® are too speculative. Her attempts to create a limited exception to these fundamental findings are without any support in the record. The relief ordered should parallel the Magistrate Judge's factual findings and the factual evidence of record.

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CERTIFICATE OF SERVICE

I hereby certify that on July 16, 2009, a copy of the foregoing **Defendants' Objections to PTO #27** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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